

that the reason the Examiner made the applicant elect a species was for the this very purpose, that is to say the applicant is able to prosecute the two patentably different species at the same time using two different applications.

### **Amendments**

#### **Claims:**

#### **Response to Claim Rejections under 35 USC § 112**

Page 3, 3<sup>rd</sup> paragraph of Office Actions Dated 091301: The presumption concerning the term “anti-HIV” is correct. As clearly taught in the specification and as know in the art any time a reference is made to an antibody to a particular substance the term “anti-particular substance is used” (e.g. anti-Alkaline phosphatase: antibody to Alkaline phosphatase) as a form of abbreviation, see enclosed attachments with reference to “anti-“. Correction will be made in the new claims. The term “anti-HIV antigen conjugated to microparticles” is supposed to be the antigen that the anti-HIV (HIV antibody) would attack is conjugated to microparticles **not** the presumption made of “HIV antibodies conjugated to microparticles”. This is made clear in the specification under “**Example 1**”, under Solution 2, it is stated that the “HIV antigen is conjugated to red microparticles”. Correction and clarity will follow. This is a complicated and technically innovative technology as taught by the specification of the present art unlike the antiquated, impractical, and time consuming technology using electrophoresis (western blotting) or ELISA of the prior art. As taught and stated in the original specification, the present art is “a significant advancement over these older techniques including ELISA, microscopic analysis, electrophoresis, two-site immunochemiluminometrics, immunofluorescent staining, zone detection, slide staining, and multiple detection layers.” The Examiner ask how the matrix is used to quantify HIV antibodies in a sample that already has HIV antibodies on it, and how will the matrix distinguishes between the reagent antibodies and sample antibodies? As taught, the following occurs: The HIV antibodies in the unknown sample competes with the HIV antibodies of the of reagent matrix. That is to say that antibodies in a test sample will compete for HIV antigen conjugated microparticles. If

there are no antibodies in the sample the HIV antigen coated particles will take up all of the active sites at the assay (test) line (forming a solid detectable line) as the HIV antibodies on the assay (test) will react with the microparticles conjugated to the HIV antigens and bonding occurs. If there are HIV antibodies in the test sample those antibodies will bond to the HIV antigen microparticles and continue to migrate past the assay (test) line and a solid line assay (test) line will not appear (again, a measurable response). Therefore, to answer the Examiner's question, the method is drawn to detecting sample antibodies. The applicant has reviewed the original specification and the order of impregnation is as follows:\*

Solution 1

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buffer  
anti-IgG

Solution 2

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buffer  
HIV antigen conjugated to red microparticles  
IgG conjugated to red microparticles

Solution 3

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Buffer  
anti-HIV

\*Of course the order of impregnation, what can be impregnated, etc., can be altered and still stay within the spirit and scope of the invention as taught in the original specification.

In order to meet the request of the Examiner concerning changes to the claim and clarification, please **Delete** Claims 11-18 and **Add** new Claims 19 – 26. The new claims should address all of the issues the Examiner had with the deleted claims 11-18 and place the application into condition for allowance.

Deleted.

19. A method for determining the presence of HIV antibodies in an unknown test sample without the use of ELISA, Western Blot and Thin Layer Liquid Phase methods for the

analysis of HIV antibodies, wherein the said method comprises the steps of preparing a test means by successfully impregnating a solid, absorbent, carrier matrix in the following order;

- a) buffer and IgG antibody; and
- b) buffer, HIV antigen conjugated to microparticles, IgG conjugated to microparticles; and
- c) buffer and HIV antibody,

drying said test means, placing test sample on test means, and determining the quantity of HIV antibodies in said test sample by comparing the relative intensity of the assay line produced to the relative intensity of the control line.

20. The method according to claim 19 wherein said HIV antibody is selected from the group consisting of HIV antibody type I or HIV antibody type II.

21. The method according to claim 19 wherein said HIV antigen is selected from the group consisting of HIV antigens type I, HIV antigen type II, or recombinant HIV antigen.

22. The method according to claim 19 in which the buffer is selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, pipes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, ampso, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, or potassium hydroxide.

23. A method for detecting HIV antibodies employing a dry chemistry test strip means to measure the HIV antibodies concentration in a test sample without the use of ELISA, Western Blot and Thin Layer Liquid Phase methods for analysis of HIV antibodies, wherein the said method comprises the steps of preparing a test means by successively impregnating an absorbent carrier matrix with reagent solutions as follows;

- a) buffer and enzyme conjugated to HIV antigen; and
- b) indicator substrate complex,

Sub. F1  
drying said test means, dipping completed test means into test sample, and determining the quantity of HIV antibodies present in said test sample by comparing the relative intensity of the color produced by the reaction of HIV antibody to the test means and comparing the color produced to a color chart with color blocks referenced to specific concentrations of HIV antibodies.

24. The method according to claim 23 wherein the said enzyme is selected from the group consisting of Galactodidase, Cellobiosidase, Arabinosidase, Fucosidase, Galactosaminidase, Glucosaminidase, Glucosidase, Glucuronidase, Lactosidase, Maltosidase, Mannosidase, or Xylosidase.

25. The method according to claim 23 wherein the said indicator substrate complex is selected from the group consisting of 5-bromo-6-chloro-3-indoxyl-beta-D-galactopyranoside, 4-Aminophenyl-beta-D-galactopyranoside, 3-indoxyl-beta-D-galactopyranoside, 5-Bromo-4-chloro-3-indoxyl-beta-D-galactopyranoside, 5-Bromo-3-indoxyl-beta-D-galactopyranoside, 6-chloro-3-indoxyl-beta-D-galactopyranoside, 6-Fluoro-3-indoxyl-beta-D-galactopyranoside, 8-Hydroxyquinoline-beta-D-galactopyranoside, 5-Iodo-3-indoxyl-beta-D-galactopyranoside, N-Methylindoxyl-beta-D-galactopyranoside, 2-Nitrophenyl-beta-D-galactopyranoside, 4-Nitrophenyl-beta-D-galactopyranoside, Naphthol AS-BI-beta-D-galactopyranoside, and 2-Naphthyl-beta-D-galactopyranoside or 4-Methylumbelliferyl-beta-D-glucuronic acid.

26. The method according to claim 23 wherein said buffer is selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, ampso, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, or potassium hydroxide.

Sub. F2  
27. A method for detecting HIV antibodies employing a dry chemistry test strip means to measure the HIV antibodies concentration in a test sample without the use of ELISA,

Western Blot and Thin Layer Liquid Phase methods for analysis of HIV antibodies, wherein the said method comprises the steps of preparing a test means by successively impregnating an absorbent carrier matrix with reagent solutions as follows;

- a) buffer, horseradish peroxidase conjugated to HIV antigen; and  
b) buffer, tetramethylbenzidine, and urea peroxide,

drying said test means, dipping completed test means into test sample, and determining the quantity of HIV antibodies present in said test sample by comparing the relative intensity of the color produced by the reaction of HIV antibody to the test means and comparing the color produced to a color chart with color blocks referenced to specific concentrations of HIV antibodies.

28. The method according to claim 27 wherein said tetramethylbenzidine can be substituted with one of the following selected from the group consisting of 2,2'-Azino-di-(3-ethylbenzthiazolinesulfonic acid) diammonium salt, 3-Amino-9-ethyl carbazole, 2,5-dimethyl-2,5-dihydroperoxyhexane, Bis{4-[N-(3'-sulfo-n-propyl)-N-n-ethyl]amino-2,6-dimethylphenyl}methane, N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methoxyaniline, N-Ethyl-N-(3-sulfopropyl)-3-methoxyaniline, N-Ethyl-N-(2-hydroxy-3-sulfopropyl)aniline, N-Ethyl-N-(3-sulfopropyl)-3,5-dimethylaniline, N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline, N-Ethyl-N-(3-sulfopropyl)-3-methylaniline, N-(3-sulfopropyl)aniline, N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxy-aniline, N-Ethyl-N-(3-sulfopropyl)-3,5-dimethoxyaniline, N-Ethyl-N-(3-sulfopropyl)aniline, N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline, N-(3-sulfopropyl)-3,5-dimethoxyaniline, N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethylaniline, N,N-Bis(4-sulfobutyl)-3,5-dimethylaniline, pyrogallol, 4-aminoantipyrine, 2,4-Dichlorophenol, N,N-Diethyl-m-toluidine, p-Hydroxybenzene Sulfonate, N,N-Dimethylaniline, 3,5-Dichloro-2-Hydroxybenzenesulfonate, Sodium N-Ethyl-N-(3-Sulfopropyl)-m-Anisidine, N-Ethyl-N-(2-hydroxy-3-Sulfopropyl)-m-toluidine 3-Methyl-2-benzothiazolinonehydrazone or Dimerhylaniline.

29. The method according to claim 27 wherein said buffer is selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, amppo, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, or potassium hydroxide.

30. A method for determining the presence of HIV antibodies in an unknown test sample without the use of ELISA, Western Blot and Thin Layer Liquid Phase methods for analysis of HIV antibodies, wherein the said method comprises the steps of preparing a test means by successfully impregnating a solid, absorbent, carrier matrix in the following order;

- a) buffer and IgG antibody; and
- b) buffer, IgG conjugated to microparticles,

drying said test means, placing test sample on test means, and determining the quantity of anti-HIV in said test sample by comparing the relative intensity of the assay line produced to the relative intensity of the control line.

31. The method according to claim 30 wherein the buffer is selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, pipes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, amppo, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, or potassium hydroxide.

32. The method according to claim 30 wherein the microparticles are selected from the group consisting of gold, rubber, latex, plastics, synthetic solids, metals or other suitable material that will form a solid platform or substrate for the covalent attachment of said IgG.